REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS

Claims 1-18 were pending in the application. Claims 2, 9-12, and 16-17 have been cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Applicant reserves the right to pursue the subject matter of the cancelled claims in this or future applications. Claims 1, 3-5, 7-8, 13-15, and 18 have been amended. Claims 19-22 are new. Support for the amended and new claims can be found throughout the specification and claims as originally filed. See, e.g., page 19, line 24; page 21, lines 18-30; and page 22, lines 1-24.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

II. THE REJECTIONS UNDER 35 U.S.C. §102(b) ARE OVERCOME

Claims 1-3, 13-15, and 18 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Lang et al. (U.S. Patent No. 5,506,112; hereinafter "Lang"). Claims 4-8 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Capon et al. (U.S. Patent No. 4,965,199; hereinafter "Capon"). The rejections are respectfully traversed and will be addressed in turn.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U .S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Turning first to the rejection over Lang, according to the Office Action, Lang teaches a method of adding a mixture of factor IXa and phospholipids to a sample containing factor VIII, wherein activated factor VIII forms a complex with factor IXa. Applicant respectfully traverses this rejection.

Applicant maintains that the pending claims are patentable over Lang. Further to the arguments of record, Lang pertains to *in vitro* assays and does not teach or suggest pharmaceutical compositions comprising pharmaceutically effective amounts of isolated coagulation factor IXa or coagulation factor VIII in a sterile injectable form.

Lang does not teach or suggest that any of the compositions should be sterile, which is clearly necessary for an injectable form. The compositions to which Lang pertains are used only in *in vitro* assays, and therefore Lang does not teach or suggest a sterile injectable form of the compositions.

Furthermore, Lang relates to a composition comprising factor IX that is dialyzed against imidazole, which is a toxic ingredient and therefore not an injectable pharmaceutical composition. Moreover, the reagent to which Lang pertains comprises factor IXa beta, factor X, thrombin and calcium ions, in amounts to render the composition effective to measure factor VIII activity. Thus, factor X and thrombin are essential components of the composition used in the method to which Lang relates, as they are needed to measure factor VIII activity. This is in contrast to the pending claims, which recite compositions consisting essentially of factors VIII and IXa.

Moreover, Lang pertains to factor VIII present in low concentrations such as 2-0.002 IU/ml. While these amounts may be appropriate for an *in vitro* assay method, they would be ineffective in a pharmaceutical composition for the treatment of hemophilia A or B, as recited in the pending claims.

Turning to the rejection over Capon, according to the Office Action, Capon teaches a method for producing factor VIII in recombinant mammalian host cells, and teaches a step where factor IXa initiates the conversion of factor X to the activated form, factor Xa; where factor VIII is currently believed to function as a cofactor and is required to enhance the activity of factor IXa and that factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals. Applicant respectfully traverses this rejection.

Applicant maintains that the pending claims are patentable over Capon. Further to the arguments of record, Capon does not teach or suggest a method of treating hemophilia A or B, comprising administering to a patient in need thereof a pharmaceutical composition consisting essentially of coagulation factors VIII and IXa.

The Examiner contends that Capon teaches that factor VIII acts together with factor IXa in the conversion of factor X to factor Xa. However, Capon does not teach that factor IXa should actually be added to the composition to which Capon pertains, let alone adding a pharmaceutically effective amount of factor IXa together with factor VIII in a pharmaceutical composition. In fact, Capon pertains to factor IXa as part of the blood clotting cascade shown in figure 1 therein and therefore factor IXa, and the other factors shown, would normally already be present inside an individual. Capon thus does not teach or suggest the addition of factor IXa to a composition comprising factor VIII for treating hemophilia A or B.

In view of the foregoing, the cited references do not anticipate the pending claims. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) are respectfully requested.